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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/699,562	10/31/2003	Tao Jiang	02307E-161500US	1597

20350 7590 07/13/2006

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EXAMINER

JONES, DAMERON LEVEST

ART UNIT PAPER NUMBER

1618

DATE MAILED: 07/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/699,562

Applicant(s)

JIANG ET AL.

Examiner

D. L. Jones

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– The MAILING DATE of this communication appears on the cover sheet with the correspondence address –
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 April 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-56 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-56 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____.

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CLARIFICATION OF RECORD

1. The office action mailed 10/18/05 is WITHDRAWN in light of the restriction set forth below.

RESTRICTION INTO GROUPS

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:

Group (1) Claims 1-41, 43-48, and 54-56, drawn to molecule products comprising A-X-B wherein SEQ ID No. 1 is utilized, classified in class 424, subclass 1.69.

Group (2) Claims 1-40, 42-48, and 54-56, drawn to molecule products comprising A-X-B wherein SEQ ID No. 2 is utilized, classified in class 424, subclass 1.69.

Group (3) Claims 1-40, 43-48, and 54-56 drawn to molecule products comprising A-X-B wherein sequences other than SEQ ID No. 1 and SEQ ID No. 2 are utilized, classified in class 424, subclass 1.69.

Group (4) Claim 49, drawn to a method of modulating cellular uptake of a peptide B comprising administering molecule products wherein X is SEQ ID No. 1, classified in class 424, subclass 9.1.

Group (5) Claim 49, drawn to a method of modulating cellular uptake of a *peptide B* comprising administering molecule products wherein X is SEQ ID No. 2, classified in class 424, subclass 9.1.

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Group (6) Claim 49, drawn to a method of modulating cellular uptake of a *peptide B* comprising administering molecule products wherein X is other than SEQ ID No. 1 and SEQ ID No. 2, classified in class 424, subclass 9.1.

Group (7) Claim 50, drawn to a method of modulating cellular uptake of a *cargo moiety C* comprising administering molecule products X is SEQ ID No. 1, classified in class 424, subclass 9.1.

Group (8) Claim 50, drawn to a method of modulating cellular uptake of a *cargo moiety C* comprising administering molecule products X is SEQ ID No. 2, classified in class 424, subclass 9.1.

Group (9) Claim 50, drawn to a method of modulating cellular uptake of a *cargo moiety C* comprising administering molecule products wherein X is other than SEQ ID No. 1 and SEQ ID No. 2, classified in class 424, subclass 9.1.

Group (10) Claims 51 and 52, drawn to nucleic acid molecules of the structures A-X-B or A-X-B-C comprising administering molecules wherein X is SEQ ID No. 1, classified in class 424, subclass 1.73.

Group (11) Claims 51 and 52, drawn to nucleic acid molecules of the structures A-X-B or A-X-B-C comprising administering molecules wherein X is SEQ ID No. 2, classified in class 424, subclass 1.73.

Group (12) Claims 51 and 52, drawn to nucleic acid molecules of the structures A-X-B or A-X-B-C comprising administering molecules wherein X is other than SEQ ID No. 1 and SEQ ID No. 2, classified in class 424, subclass 1.73.

Group (13) Claim 53, drawn to a fluorescent molecule products of the formula Q-A-X-B-C wherein X is SEQ ID No. 1, classified in class 424, subclass 1.73.

Group (14) Claim 53, drawn to a fluorescent molecule products of the formula Q-A-X-B-C wherein X is SEQ ID No. 2, classified in class 424, subclass 1.73.

Group (15) Claim 53, drawn to a fluorescent molecule products of the formula Q-A-X-B-C wherein X is other than SEQ ID No. 1 and SEQ ID No. 2, classified in class 424, subclass 1.73.

Note: Claims appearing in more than one Group will only be examined to the extent that they read on the elected invention.

3. The inventions are distinct, each from the other because of the following reasons: Inventions {(1) – (3) and (10) – (15)} and {(4) – (9)} are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the products Groups {(1) – (3) and (10) – (15)} may be utilized with one or more of the methods of claims. of modulating cellular uptake of a peptide or cellular uptake of a cargo moiety.

Note: It should be noted that while some of the inventions classify in the same subclass, a separate search is required since the sequences present in each of the products is distinct from one another.

4. Inventions (1) - (3), (10) - (12), and (13) - (15) unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions are distinct from one another because Groups (13) – (15) are directed to fluorescent labeled molecules, Groups (10) – (12) are directed to nucleic acids, and Groups (1) – (3) are directed to non-labeled molecules.

Note: It should be noted that while some of the inventions classify in the same subclass, a separate search is required since the sequences present in each of the products is distinct from one another.

5. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

REJOINDER PARAGRAPH

6. The Examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product will be entered as a**

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matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

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ELECTION OF SPECIES

7. Claims 1-56 are generic to a plurality of disclosed patentably distinct species comprising various sequences that incorporate the molecule structure A-X-B and methods of modulating cellular uptake using the molecules as set forth in independent claims 1, 11, 46, 49, 50, 51, 52, and 53. The variable A is a peptide having about 2 to about 20 acidic amino acid residues. The variable B is a peptide having about 5 to about 20 basic amino acid residues. The variable X is a linker having about 2 to about 100 atoms. In addition, the variable C which is a fluorescent cargo moiety may be present. Likewise, the variable Q which is a quencher moiety may be present. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species from within the elected Group above for search purposes, even though this requirement is traversed.

Note: Applicant is respectfully requested to elect a single disclose species from within the elected group for search purposes. If appropriate for the elected group, Applicant is respectfully requested to identify the species represented by the variables A, B, X, C, and Q.

8. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over

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the prior art, the evidence or admission may be used in a rejection under 35

U.S.C. 103(a) of the other invention.

9. Due to the complexity of the restriction requirement, a telephone call was not made to request an oral election to the above restriction requirement.

10. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement is traversed (37 CFR 1.143).


11. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. L. Jones whose telephone number is (571) 272-0617. The examiner can normally be reached on Mon.-Fri., 6:45 a.m. - 3:15 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



D. L. Jones
Primary Examiner
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July 7, 2006